



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 7**

11201 Renner Boulevard  
Lenexa, Kansas 66219

**AUG 01 2016**

**CERTIFIED MAIL**

**RETURN RECEIPT REQUESTED**

Article Number: 7014 1200 0000 6126 5018

Ms. Karen Richards  
Plant Manager  
Valent Bio Sciences Corporation  
2142 350<sup>th</sup> Street  
Osage, Iowa 50461

RE: Valent Bio Sciences  
Osage, Iowa  
RCRA ID No.: IAR000519736

Dear Ms. Richards:

**Letter of Warning/Request for Information**

On October 27, 2015, a representative of the U. S. Environmental Protection Agency inspected your facility. The inspection was conducted under the authority of Section 3007 of the Resource Conservation and Recovery Act.


My staff has reviewed the inspection report, and your November 29, 2015 response to the Notice of Preliminary Findings and have determined that violations of RCRA were documented. We are requesting additional information regarding your facility's compliance status. Enclosed is a list of violations followed by a list of questions and/or requested information. Also enclosed are instructions to be used in providing your response. Please carefully read and follow these instructions. Your response to this request in accordance with the instructions is required by Section 3007 of RCRA and substantial penalties may result from not complying. Please note that the EPA reserves its right to pursue appropriate enforcement actions, including penalties, for violations discovered as a result of the inspection, regardless of whether the violations were subsequently corrected.



Printed on Recycled Paper

Within 30 calendar days of receiving this letter, please mail your response to: Rebecca Wenner, U. S. Environmental Protection Agency, 11201 Renner Boulevard, Lenexa, Kansas, 66219. To request an extension of the time limit, follow the instructions in the enclosure. Please direct all questions concerning this letter to Rebecca Wenner, of my staff, at (913) 551-7644.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Goetz", with a long horizontal flourish extending to the right.

Mary Goetz  
Chief

Waste Enforcement and Materials Management Branch  
Air and Waste Management Division

Enclosures (3)

cc: Amie Davidson, Supervisor, Contaminated Sites Section  
Iowa Department of Natural Resources

**List of Violations**  
**Osage, Iowa**  
**RCRA ID No.: IAR000519736**

1. 40 CFR 262.11 - Failure to determine if solvent contaminated wipes are hazardous waste.

Requested Information  
Valent Bio Sciences Corporation  
Osage, Iowa  
RCRA ID No.: IAR000519736

1. Please identify all persons responding to the questions in this letter. Please include names, titles, and telephone numbers, if different from the facility's telephone number.
2. In your November 2015 response, you provided copies of analytical results showing that the solvent contaminated wipes are not characteristic hazardous waste, but you did not provide any information to indicate that you determined whether or not the wipes are a listed hazardous waste. In particular, the inspector was concerned that the waste might be an F-listed hazardous waste according to 40 CFR 261.31, Hazardous wastes from non-specific sources. In order to determine if your solvent contaminated wipes are a listed hazardous waste, you will need to review the Safety Data Sheets and other documents that might provide information as to the percentages and types of solvents being used on the wipes. Using this knowledge, you can determine whether or not your solvent contaminated wipes are a listed hazardous waste or not. Once this is completed, please send your determination, along with legible copies of all , documents (Safety Data Sheets or other documents) used to make the determination.

Please be aware that the Solvent Contaminated Wipes Rule became effective in Iowa in early 2014. Generators of hazardous waste can choose to manage solvent contaminated wipes under this rule if their wipes do not contain free liquids and if they meet the other requirements of the rule (labeling, free liquids restrictions, containerization requirements, accumulation time limits, record keeping). This rule applies to solvent contaminated wipes that are being laundered (reusable) and disposed, however the requirements are slightly different for each. The most notable difference is that disposable wipes contaminated with trichloroethylene and are disposed of in a landfill cannot be managed under this rule and must be managed as hazardous waste. More specific requirements can be found at the following website: <https://www.epa.gov/hwgenerators/final-rule-2013-conditional-exclusions-solid-waste-and-hazardous-waste-solvent>. If you are considering managing your solvent contaminated wipes under this rule, please include the information in your report explaining how you will manage your wipes to meet the requirements of this rule.

### 3007 RESPONSE INSTRUCTIONS

- \* Identify the Person(s) responding to this request on your behalf.
- \* Address each numbered item separately, and precede each answer with the number of the item to which it responds.
- \* For each numbered item, identify all documents consulted, examined, or referred to in the preparation of the answer, or that contain information responsive to the requested item. Provide true, accurate, and legible copies of all such documents. (If information responsive to an item is available but there are no relevant source documents, you must still provide the information.)
- \* For each document provided, indicate on the document (or in some similar manner) the number of the item to which it responds.
- \* For each numbered item, identify all persons consulted in the preparation of the answer.
- \* For purposes of this request, the term "you" or "your" refers to the company, corporation and any officer, principal, agent employee, or any other person(s) associated in any capacity.
- \* If information responsive to a requested item is not in your possession, identify the person(s) from whom the information may be obtained.
- \* If information that is not known or available at the time you make your response later becomes known or available to you, you must supplement your response.
- \* If, at any time after you submit your response, you find that any part of the information you submitted is incomplete, false, or misrepresents the truth, you must notify the EPA immediately.
- \* You must provide the requested information even though you consider it confidential information or trade secrets. If you want to make a confidentiality claim covering part or all of the information submitted, identify the material with words such as "trade secret," "proprietary," or "company confidential."
- \* The EPA will disclose this information only to the extent and by the means described in 40 CFR Part 2, Subpart B., provided that it qualifies as confidential business information.
- \* A request for an extension to the time limit for responding must be in writing and must be postmarked within five (5) calendar days of receipt of this information request. Address it to the person identified in the cover letter to receive your response.
- \* Copies of the Code of Federal Regulations may be obtained from the U.S. Government Bookstores or on the Internet at [www.epa.gov/epahome/cfr40.htm](http://www.epa.gov/epahome/cfr40.htm).
- \* This request for information is not subject to the approval requirements of the Paperwork Reduction Act of 1980.
- \* The EPA encourages you to conserve resources. Suggested methods include use of recycled paper, printing on both sides (duplex printing), and when possible submitting documents electronically (i.e., email or compact discs). If hard copy submittals are necessary, please do not submit documents in binders.

Not responding to this information request within the stated time limit and in accordance with these instructions may subject your facility to an enforcement action which could include the imposition of penalties of up to \$37,500 per violation, per day of continued noncompliance. Providing false, fictitious, or fraudulent statements or representations could lead to criminal penalties.

